# General

## Guideline Title

Mental health of adults in contact with the criminal justice system.

## Bibliographic Source(s)

National Guideline Alliance. Mental health of adults in contact with the criminal justice system. London (UK): National Institute for Health and Care Excellence (NICE); 2017 Mar 21. 40 p. (NICE guideline; no. 66).

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Guideline Alliance on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices. See the original guideline document for definition of terms used in this guideline.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

Using This Guideline Together with Other NICE Guidelines

Use this guideline with the NICE guidelines on service user experience in adult mental health and patient experience in adult NHS services to improve the experience of care for people with mental health problems including those with neurodevelopmental disorders.

Use this guideline with any NICE guidelines on specific mental health problems. (Note: This guideline covers the full range of mental health problems including common mental disorders, substance misuse disorders, neurodevelopmental disorders and personality disorders.) Take into account:

- The nature and severity of any mental health problem
- The presence of a learning disability or any acquired cognitive impairment
- Other communication difficulties (for example, language, literacy, information processing or sensory deficit)
- The nature of any coexisting mental health problems (including substance misuse)

- Limitations on prescribing and administering medicine (for example, in-possession medicine) or the timing of the delivery of interventions in certain settings (for example, prison)
- The development of trust in an environment where health and care staff may be held in suspicion
- Any cultural and ethnic differences in beliefs about mental health problems
- Any differences in presentation of mental health problems
- The setting in which the assessment or treatment takes place

Obtain, evaluate and integrate all available and reliable information about the person when assessing or treating people in contact with the criminal justice system. For example:

- Person escort record (PER)
- Pre-sentence report
- All medical records
- Custody reports
- Assessment, Care in Custody and Teamwork (ACCT) document
- Reports from other relevant services, including liaison and diversion, substance misuse services, social service or housing services and youth offending services
- Offender Assessment System (OASys) or other assessment tools

Take into account how up to date the information is and how it was gathered.

Principles of Assessment

Work with a family member, partner, carer, advocate or legal representative when possible in order to get relevant information and support the person, help explain the outcome of assessment and help them make informed decisions about their care. Take into account:

- The person's wishes
- The nature and quality of family relationships, including any safeguarding issues
- Any statutory or legal considerations that may limit family and carer involvement
- The requirements of the Care Act 2014

Carry out assessments:

- In a suitable environment that is safe and private
- In an engaging, empathic and non-judgemental manner

When assessing a person, make reasonable adjustments to the assessment that take into account any suspected neurodevelopmental disorders (including learning disabilities), cognitive impairments, or physical health problems or disabilities. Seek advice or involve specialists if needed.

Identification and Assessment throughout the Care Pathway

Be vigilant for the possibility of unidentified or emerging mental health problems in people in contact with the criminal justice system, and review available records for any indications of a mental health problem.

Ensure all staff working in criminal justice settings are aware of the potential impact on a person's mental health of being in contact with the criminal justice system.

First-Stage Health Assessment at Reception into Prison

The following recommendations cover what happens when a person first arrives into prison, and are taken from the NGC summary of the NICE guideline Physical health of people in prison. They refer to the first-stage health assessment, which is a combined physical and mental health assessment. A second-stage mental health assessment in prison should normally be done within 7 days.

At first reception into prison, a healthcare professional (or trained healthcare assistant under the supervision of a registered nurse) should carry out a health assessment for every person. Do this before the person is allocated to their cell. As part of the assessment, identify:

- Any issues that may affect the person's immediate health and safety before the second-stage health assessment
- Priority health needs to be addressed at the next clinical opportunity

Ensure continuity of care for people transferring from one custodial setting to another (including court, the receiving prison or during escort periods)

by, for example:

- Accessing relevant information from the patient clinical record, prisoner escort record and cell sharing risk assessment
- Checking medicines and any outstanding medical appointments

The first-stage health assessment should include the questions and actions in Table 1 of the original guideline document (there is also a downloadable version of this table). It should cover:

- Physical health
- Alcohol use
- Substance misuse
- Mental health
- Self-harm and suicide risk

Identification and Assessment throughout the Care Pathway (Including Second-Stage Health Assessment in Prisons)

The following recommendations apply both throughout the care pathway and to the second-stage health assessment in prisons. In non-prison settings, all staff should think about using the Correctional Mental Health Screen tool.

Consider using the Correctional Mental Health Screen for Men (CMHS-M) or Women (CMHS-W) to identify possible mental health problems if:

- The person's history, presentation or behaviour suggest they may have a mental health problem
- The person's responses to the first-stage health assessment suggest they may have a mental health problem
- The person has a chronic physical health problem with associated functional impairment
- Concerns have been raised by other agencies about the person's abilities to participate in the criminal justice process

When using the CMHS-M or CMHS-W with a transgender person, use the measure that is in line with their preferred gender identity.

If a man scores 6 or more on the CMHS-M, or a woman scores 4 or more on the CMHS-W, or there is other evidence supporting the likelihood of mental health problems, practitioners should:

- Conduct a further assessment if they are competent to perform assessments of mental health problems or
- Refer the person to an appropriately trained professional for further assessment if they are not competent to perform such assessments themselves

Carrying Out a Mental Health Assessment

Service providers should ensure that competent practitioners who have experience of working with people in contact with the criminal justice system with mental health problems:

- Perform the mental health assessment
- Coordinate the input of other professionals into the assessment when needed

If there are concerns about a person's mental capacity, practitioners should:

- Perform a mental capacity assessment if they are competent to do this (or refer the person to a practitioner who is)
- Consider involving an advocate to support the person

All practitioners should discuss rights to confidentiality with people and explain:

- What the mental health assessment is for and how the outcome of the assessment may be used
- How consent for sharing information with named family members, carers and other services should be sought
- That the assessor may have a legal or ethical duty to disclose information relating the safety of the person or others, or to the security of the institution

All practitioners should ensure mental health assessment is a collaborative process that:

- Involves negotiation with the person, as early as possible in the assessment process, about how information about them will be shared with others involved in their care
- Makes the most of the contribution of everyone involved, including the person, those providing care or legal advice and family members and carers

- Engages the person in an informed discussion of treatment, support and care options
- Allows for the discussion of the person's concerns about the assessment process

Ensure all practitioners carrying out mental health assessments are competent to assess problems that commonly present, with an understanding of the context and setting in which they are done. They should:

- Tailor the content, structure and pace of an assessment to the person's needs and adjust the assessment as new information emerges
- Take into account the person's understanding of the problem
- Have knowledge and awareness of diagnostic classification systems and their limitations
- Appraise the reliability and validity of all available health and criminal justice systems records
- Identify and take into account the reasons for any significant differences between the assessor's views and those of the person and other agencies involved in their care
- Use validated tools relevant to the disorders or problems being assessed
- Take into account the views of practitioners from other services involved in the person's care

All practitioners carrying out mental health assessment should take into account the following when conducting an assessment of suspected mental health problems for people in contact with the criminal justice system:

- The nature and severity of the presenting mental health problems (including cognitive functioning) and their development and history
- Coexisting mental health problems
- Coexisting substance misuse problems, including novel psychoactive substances
- Coexisting physical health problems
- Social and personal circumstances, including personal experience of trauma
- Social care, educational and occupational needs
- People's strengths
- Available support networks, and the person's capacity to make use of them
- Previous care, support and treatment, including how the person responded to these
- Offending history and how this may interact with mental health problems

When assessing people in contact with the criminal justice system all practitioners should:

- Recognise potential barriers to accessing and engaging in interventions and methods to overcome these at the individual and service level
- Discuss mental health problems and treatment options in a way that gives rise to hope and optimism by explaining that change is possible and attainable
- Be aware that people may have negative expectations based on earlier experiences with mental health services, the criminal justice system, or other relevant services

All practitioners should share the outcomes of a mental health assessment, in accordance with legislation and local policies, subject to permission from the person where necessary, with:

- The person and, if possible, their family members or carers
- All staff and agencies (for example, probation service providers and secondary care mental health services) involved in the direct development and implementation of the plan
- Other staff or agencies (as needed) not directly involved in the development and implementation of the plan who could support the effective implementation and delivery of the plan

Reviewing the Mental Health Assessment

Practitioners should review and update mental health assessments:

- If new information is available about the person's mental health problem
- If there are significant differences between the views of the person and the views of the family, carers or staff that cannot be resolved through discussion
- When major legal or life events occur
- When the person is transferred between, or out of, criminal justice services
- If a person experiences a significant change in care or support, for example, stopping an Assessment, Care in Custody and Teamwork (ACCT) plan
- If a person disengages or does not stick to their treatment plan

- Annually, or as required by local policy such as Care Programme Approach or Care Treatment Plan

When updating mental health assessments, practitioners should consider:

- Reviewing and ensuring demographic information is accurate
- Reviewing psychological, social, safety, personal historical and criminological factors
- Assessing multiple areas of need, including social and personal circumstances, physical health, occupational rehabilitation, education and previous and current care and support
- Developing an increased understanding of the function of the offending behaviour and its relationship with mental health problems
- Covering any areas not fully explored by the initial assessment

Risk Assessment and Management

Perform a risk assessment for all people in contact with the criminal justice system when a mental health problem occurs or is suspected.

All practitioners should take into account the following issues in risk assessments for people in contact with the criminal justice system:

- Risk to self, including self-harm, suicide, self-neglect, risk to own health and degree of vulnerability to exploitation or victimisation
- Risk to others that is linked to mental health problems, including aggression, violence, exploitation and sexual offending
- Causal and maintaining factors
- The likelihood, imminence and severity of the risk
- The impact of their social and physical environment
- Protective factors that may reduce risk

During a risk assessment the practitioner doing the assessment should explain to the person that their behaviours may need to be monitored. This may include:

- External monitoring of behaviours that may indicate a risk to self or others
- Self-monitoring of risk behaviours to help the person to identify, anticipate and prevent high-risk situations

If indicated by their risk assessment, the practitioner doing the assessment should develop a risk management plan for a person. This should:

- Integrate with or be consistent with the mental health assessment and plan
- Take an individualised approach to each person and recognise that risk levels may change over time
- Set out the interventions to reduce risk at the individual, service or environmental level
- Take into account any legal or statutory responsibilities which apply in the setting in which they are used
- Be shared with the person (and their family members or carers if appropriate) and relevant agencies and services subject to permission from the person where necessary
- Be reviewed regularly by those responsible for implementing the plan and adjusted if risk levels change

All practitioners should ensure that any risk management plan is:

- Informed by the assessments and interventions in relevant NICE guidance for the relevant mental health disorders, including the NICE guidelines on self-harm in over 8s: short-term management and prevention of recurrence and self-harm in over 8s: long-term management
- Implemented in line with agreed protocols for safeguarding vulnerable people and the provision of appropriate adults
- Implemented in line with agreed protocols in police custody, prisoner escort services, prison, community settings and probation service providers

Ensure that the risk management plan is integrated with, and recorded in, the relevant information systems; for example, the ACCT procedure in prisons, the Offender Assessment System (OASys) and SystmOne and Multi-Agency Risk Assessment Conference (MARAC) and Multi-Agency Public Protection Arrangements (MAPPA).

Care Planning

Develop a mental health care plan in collaboration with the person and, when possible, their family, carers and advocates. All practitioners developing the plan should ensure it is integrated with care plans from other services, and includes:

- A profile of the person's needs (including physical health needs), identifying agreed goals and the means to progress towards them

- Identification of the roles and responsibilities of those practitioners involved in delivering the care plan
- The implications of any mandated treatment programmes, post-release licences and transfer between institutions or agencies, in particular release from prison
- A clear strategy to access all identified interventions and services
- Agreed outcome measures and timescale to evaluate and review the plan
- A risk management plan and a crisis plan if developed
- An agreed process for communicating the care plan (such as the Care Programme Approach or Care Treatment Plan) to all relevant agencies, the person, and their families and carers, subject to permission from the person where necessary

When developing or implementing a mental health care plan all practitioners should take into account:

- The ability of the person to take in and remember information
- The need to provide extra information and support to help with the understanding and implementation of the care plan
- The need for any adjustment to the social or physical environment
- The need to adjust the structure, content, duration or frequency of any intervention
- The need for any prompts or cognitive aids to help with delivery of the intervention

Psychological Interventions

Delivering Psychological Interventions for Mental Health Problems

Refer to relevant NICE guidance for the psychological treatment of mental health problems for adults in contact with the criminal justice system, taking into account the need:

- To modify the delivery of psychological interventions in the criminal justice system
- To ensure continuity of the psychological intervention (for example, transfer between prison settings or on release from prison)
- For staff to be trained and competent in the interventions they are delivering
- For supervision
- For audit using routinely available outcome measures

Be aware that many people in contact with the criminal justice system (including people with a diagnosis of personality disorder) may have difficulties with:

- Accurately interpreting and controlling emotions
- Impulse control (for example, difficulty planning, seeking high levels of stimulation, ambivalent about consequences of their negative actions)
- Experiencing themselves as having a lack of autonomy (for example, seeing their actions as pointless, having difficulties in setting and achieving goals)
- Having an unstable sense of self that varies depending on context or is influenced by the people they interact with
- Social functioning (for example, relating to, cooperating with and forming relationships with others, difficulties understanding their own and others' needs)
- Occupational functioning

Personality Disorder

Providers of services should ensure staff are able to identify common features and behaviours associated with personality disorders and use these to inform the development of programmes of care.

Practitioners should ensure interventions for people with a diagnosis of personality disorder or associated problems are supportive, facilitate learning and develop new behaviours and coping strategies in the following areas:

- Problem solving
- Emotion regulation and impulse control
- Managing interpersonal relationships
- Self-harm
- Use of medicine (including reducing polypharmacy)

Practitioners should be aware when delivering interventions for people with mental health problems that having a personality disorder or an associated problem may reduce the effectiveness of interventions. Think about:

- Providing additional support
- Adjusting the duration and intensity of psychological interventions if standard protocols have not worked
- Delivering complex interventions in a multidisciplinary context

Practitioners should not exclude people with personality disorders from any health or social care service, or intervention for comorbid disorders, as a direct result of their diagnosis.

Specific Psychological Interventions

Practitioners should consider using contingency management to reduce drug misuse and promote engagement with services for people with substance misuse problems.

Practitioners delivering contingency management programmes should:

- Agree with the person the behaviour that is the target of change
- Provide incentives in a timely and consistent manner
- Confirm the person understands the relationship between the treatment goal and the incentive schedule
- Make incentives reinforcing and supportive of a healthy and drug-free lifestyle

Practitioners should consider referral to a therapeutic community specifically for substance misuse for people in prison with a minimum 18-month sentence who have an established pattern of drug misuse.

When setting up therapeutic community programmes in prison settings in a separate wing of a prison for people with substance misuse problems, aim to:

- Include up to 50 prisoners in the programme
- Provide treatment for between 12 and 18 months, made up of:
    - Twice-weekly group therapy sessions (mean group size of 8)
    - Daily (5 days only) community meeting for all wing residents
    - Daily (5 days only) social activity groups for all wing residents
    - A once-weekly individual review meeting (20 minutes)

Consider psychological interventions for paraphilias only when delivered as part of a research programme.

Pharmacological Interventions

Refer to relevant NICE guidance for pharmacological interventions for mental health problems in adults in contact with the criminal justice system. Take into account:

- Risks associated with in-possession medicines
- Administration times for medication
- Availability of medicines in the first 48 hours of transfer to prison
- Availability of medicines after release from prison

Refer to the NGC summary of the NICE guideline Attention deficit hyperactivity disorder: diagnosis and management when prescribing pharmacological interventions for this condition.

Review all medicines prescribed for sleep problems and the management of chronic pain to:

- Establish the best course of treatment (seek specialist advice if needed)
- Assess the risk of diversion or misuse of medicines

Organisation of Services

Service Structures and Delivery

Commissioners and providers of criminal justice services and healthcare services should support the development of liaison and diversion functions for police custody and the courts that provide prompt access to the following:

- The effective identification and recognition of mental health problems
- A comprehensive mental health assessment

- Advice on immediate care and management
- Appropriate treatment and care (including medication)

Providers of criminal justice services and healthcare services should consider diverting people from standard courts to dedicated drug courts if the offence is linked to substance misuse and was non-violent.

Commissioners and providers of criminal justice services and healthcare services should consider establishing joint working arrangements between healthcare, social care and police services for managing urgent and emergency mental health presentations in the community (for example, street triage). Include:

- Joint training for police, healthcare and social care staff
- Agreed protocols for joint working developed and reviewed by a multi-agency group
- Agreed protocols for effective communication within and between agencies
- Agreed referral pathways for urgent and emergency care and routine care

Commissioners and providers of criminal justice services and healthcare services should ensure effective identification, assessment, coordination and delivery of care for all people with a mental health problem in contact with the criminal justice system. This should include people who are transferring from young offender services and those on probation. In particular, ensure that:

- All people with a severe or complex mental health problem have a designated care coordinator
- During transitions between services care plans are shared and agreed between all services
- Effective protocols are in place to support routine data sharing and, when necessary, joint plans of care between health services (including primary and secondary care services) and criminal justice agencies to reduce unnecessary assessments and promote effective interventions

Staff Training

Commissioners and providers of criminal justice services and healthcare services should ensure that all staff working in the criminal justice system, who provide direct care or supervision, have a comprehensive induction, covering:

- The purpose of the service in which they work, and the role and availability of other related local services, including pathways for referral
- The roles, responsibilities and processes of criminal justice, health and social care staff
- Legislation and local policies relevant to their role, for sharing information with others involved in the person's care
- Protocols for dealing with mental health problems in the criminal justice system (for example, in-possession medicines, side effects, withdrawal)
- The importance of clear communication, including avoiding acronyms and using consistent terminology

Commissioners and providers of criminal justice services and healthcare services should educate all staff about:

- The stigma and discrimination associated with mental health problems and associated behaviours, such as self-harm
- The need to avoid judgemental attitudes
- The need to avoid using inappropriate terminology

Provide multidisciplinary and multi-agency training (as part of both induction training and continuing professional development) to increase consistency, understanding of ways of working, and promotion of positive working relationships for all staff who work in the criminal justice system on:

- The prevalence of mental health problems in the criminal justice system, and why such problems may bring people into contact with the criminal justice system
- The main features of commonly occurring mental health problems seen in the criminal justice system, and the impact these may have on behaviour and compliance with rules and statutory requirements
- Recognising and responding to mental health problems and communication problems that arise from, or are related to, physical health problems

Give all staff involved in direct care, training (as part of induction training and continuing professional development) and supervision to support them in:

- Dealing with critical incidents, including emergency life support
- Managing stress associated with working in the criminal justice system and how this may affect their interactions with people and their own mental health and wellbeing

- The recognition, assessment, treatment and management of self-harm and suicide
- De-escalation methods to minimise the use of restrictive interventions
- Recognition of changes in behaviour, taking into account that these may indicate the onset of, or changes to, mental health problems
- Knowledge of effective interventions for mental health problems
- Developing and maintaining safe boundaries and constructive relationships
- Delivering interventions within the constraints of the criminal justice system (for example, jail craft training, formulation skills

Definitions

Strength of Recommendations

Some recommendations can be made with more certainty than others, depending on the quality of the underpinning evidence. The Guideline Committee makes a recommendation based on the trade-off between the benefits and harms of a system, process or an intervention, taking into account the quality of the underpinning evidence. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

*Interventions That Must (or Must Not) Be Used*

The Guideline Committee usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the Guideline Committee uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

*Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation*

The Guideline Committee uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of people, a system, process or an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the Guideline Committee is confident that an intervention will not be of benefit for most people.

*Interventions That Could Be Used*

The Guideline Committee uses 'consider' when confident that a system, process or an intervention will do more good than harm for most people, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the person's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the person.

## Clinical Algorithm(s)

A National Institute for Health and Care Excellence interactive flowchart titled "Health of people in the criminal justice system overview" is available from the NICE Web site .

# Scope

## Disease/Condition(s)

Mental health problems including common mental health problems, severe mental illness, personality disorders, drug and alcohol problems, paraphilias, neurodevelopmental disorders and acquired cognitive impairment

## Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

## Clinical Specialty

Psychiatry

Psychology

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Other

Patients

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Substance Use Disorders Treatment Providers

Utilization Management

## Guideline Objective(s)

- To make recommendations for the identification and management of mental health problems and integration of care for adults in contact with the criminal justice system
- To improve access and engagement with treatment and services for people with mental health problems who are in contact with the criminal justice system
- To evaluate the role of specific psychological, psychosocial and pharmacological interventions in the treatment of mental health problems within the criminal justice system
- To evaluate the role of specific service-level interventions for people with mental health disorders in contact with the criminal justice system
- To integrate the above to provide best-practice advice on the care of individuals throughout the course of their treatment
- To promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the National Health Service (NHS) in England and Wales

## Target Population

Adults (aged 18 and over) with, or at risk of developing, a mental health problem who are in contact with the criminal justice system

Note: This guideline covers people in police custody; in court custody; in contact with liaison, diversion and street triage services; remanded on bail; remanded in prison; who have been convicted and are serving a prison or community sentence; released from prison on licence; and released from prison and in contact with a community rehabilitation company (CRC) or the probation service. Specific consideration will be given to people with neurodevelopmental disorders (including learning disabilities), women, older adults (aged 50 years

and over), young black men, and young adults that have transitioned from juvenile services. The guideline will also be relevant to, but will not cover, practice involving people who are cared for in hospital, except for providing guidance on managing transitions between criminal justice system settings and hospital; people in immigration removal centres; children and young people (aged under 18 years); people who are in contact with the criminal justice system solely as a result of being a witness or victim.

## Interventions and Practices Considered

Evaluation/Risk Assessment

1. Using the guideline recommendations together with other National Institute for Health and Care Excellence (NICE) mental health guidelines
2. Obtaining, evaluating and integrating all available and reliable information about the person
3. Principles of assessment
4. Identification and assessment throughout the care pathway
    - First-stage health assessment at reception into prison
    - Second-stage health assessment in prisons
    - Carrying out a mental health assessment
    - Reviewing the mental health assessment
5. Risk assessment and management
6. Care planning

Treatment/Management/Prevention

1. Psychological interventions
    - Delivering psychological interventions for mental health problems
    - Interventions for personality disorders
    - Specific psychological interventions (e.g., contingency management to reduce drug misuse, therapeutic community programs)
2. Pharmacological interventions with reference to relevant NICE guidance for pharmacological interventions for mental health problems in adults, attention-deficit hyperactivity disorder (ADHD), sleep problems, and pain
3. Organisation of services (service structure and delivery)
4. Staff training

## Major Outcomes Considered

- Mental health outcomes
- Offending and re-offending
- Service use
- Adaptive functioning (for example, employment status both within and outside of prison, development of daily living and interpersonal skills and quality of life)
- Rates of self-injury in service users
- Experience of care
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

# Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Guideline Alliance (NGA) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Review Protocols

Review questions drafted during the scoping phase were discussed by the Guideline Committee (GC) at the first few meetings and amended as necessary. The review questions were used as the starting point for developing review protocols for each systematic review. Where appropriate, the review questions were refined once the evidence had been searched and, where necessary, sub-questions were generated. The final list of review questions can be found in Appendix F.

For questions about interventions, the PICO (Population, Intervention, Comparison and Outcome) framework was used to structure each question (see Table 2 in the full version of the guideline).

Questions relating to case identification and assessment tools and methods do not involve an intervention designed to treat a particular condition and therefore the PICO framework was not used. Rather, the questions were designed to pick up key issues specifically relevant to clinical utility, for example their accuracy, reliability, safety and acceptability to the service user.

In some situations, the prognosis of a particular condition is of fundamental importance, over and above its general significance in relation to specific interventions. Areas where this is particularly likely to occur relate to assessment of risk, for example in terms of behaviour modification or screening and early intervention. In addition, review questions related to issues of service delivery are occasionally specified in the remit from the Department of Health/Welsh Assembly Government. In these cases, appropriate review questions were developed to be clear and concise.

Where review questions about service user experience were specified in the scope, the SPICE format was used to structure the questions (see Table 3 in the full version of the guideline).

For each topic, addressed by one or more review questions, a review protocol was drafted by the NGA technical team using a standardised template (based on PROSPERO), reviewed and agreed by the GC (all protocols are included in Appendix F of the full guideline).

To help facilitate the literature review, a note was made of the best study design type to answer each question. There are five main types of review question of relevance to NICE guidelines. These are listed in Table 4 of the full version of the guideline. For each type of question, the best primary study design varies, where 'best' is interpreted as 'least likely to give misleading answers to the question'. For questions about the effectiveness of interventions, where randomised controlled trials (RCTs) were not available, the review of other types of evidence was pursued only if there was reason to believe that it would help the GC to formulate a recommendation.

However, in all cases, a well-conducted systematic review (of the appropriate type of study) is likely to always yield a better answer than a single study.

Clinical Review Methods

Scoping Searches

A broad preliminary search of the literature was undertaken in July 2014 to obtain an overview of the issues likely to be covered by the scope and to help define key areas. The searches were restricted to clinical guidelines, Health Technology Assessment (HTA) reports, key systematic reviews and RCTs. A list of databases and Web sites searched can be found in Appendix H.

Systematic Literature Searches

After the scope was finalised, a systematic search strategy was developed to locate as much relevant evidence as possible. The balance between sensitivity (the power to identify all studies on a particular topic) and specificity (the ability to exclude irrelevant studies from the results) was carefully considered and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to certain study designs if specified in the review protocol and conducted in the following databases:

- Cochrane Database of Abstracts of Reviews of Effects (DARE)
- Cochrane Database of Systematic Reviews (CDSR)
- CENTRAL
- EMBASE
- Health Technology Assessment (HTA) database

- MEDLINE/MEDLINE In-Process
- Psychological Information Database (PsycINFO)

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches and discussions of the results of the searches with the review team and GC to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for mental health and the criminal justice system were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms and imprecise reporting of study populations by authors in the titles and abstracts of records. The search terms for each search are set out in full in Appendix H.

Reference Management

Citations from each search were downloaded into reference management software and duplicates removed. Records were then screened against the eligibility criteria of the reviews before being appraised for methodological quality. The unfiltered search results were saved and retained for future potential re-analysis to help keep the process both replicable and transparent.

Search Filters

To aid retrieval of relevant and sound studies, filters were used to limit a number of searches to systematic reviews, RCTs and qualitative studies. The search filters for systematic reviews and RCTs are adaptations of validated filters designed by the Health Information Research Unit (HIRU) at McMaster University. The qualitative research filter was developed in-house. Each filter comprises index terms relating to the study type(s) and associated text words for the methodological description of the design(s). The filters have been recorded and can be found listed in the search strategies in Appendix H.

Date and Language Restrictions

Systematic database searches were initially conducted in February 2015 up to the most recent searchable date. Search updates were generated on a six-monthly basis, with the final re-runs carried out in June 2016 ahead of the guideline consultation. After this point, studies were only included if they were judged by the GC to be exceptional (for example, if the evidence was likely to change a recommendation).

Although no language restrictions were applied at the searching stage, foreign language papers were not requested or reviewed, unless they were of particular importance to a review question.

Date restrictions were not applied, except for searches of systematic reviews which were limited to research published from 2000. The search for systematic reviews was restricted to the last 15 years as older reviews were thought to be less useful.

Other Search Methods

Other search methods involved: (a) scanning the reference lists of all eligible publications (systematic reviews and stakeholder evidence) for more published reports and citations of unpublished research; (b) tracking key papers in the Science Citation Index (prospectively) over time for further useful references; (c) conducting searches in ClinicalTrials.gov for unpublished trial reports; (d) contacting included study authors for unpublished or incomplete datasets. Searches conducted for existing NICE guidelines were updated where necessary. Other relevant guidelines were assessed for quality using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument. The evidence base underlying high-quality existing guidelines was utilised and updated as appropriate.

Full details of the search strategies and filters used for the systematic review of clinical evidence are provided in Appendix H of the full version of the guideline.

Study Selection and Assessment of Methodological Quality

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database (standardised template created in Microsoft Excel). Specific eligibility criteria were developed for each review question and are described in the relevant clinical evidence chapters (see the full version of the guideline).

Eligible systematic reviews were critically appraised for methodological quality (risk of bias) using a checklist (see *The Guidelines Manual* [NICE, 2014] for template [see the "Availability of Companion Documents" field]). Primary intervention studies were appraised using a checklist based on the Cochrane Risk of Bias tool, but with additional items for non-randomised studies (e.g., non-random allocation method and confounders) and for indirectness and imprecision (see Appendices I, J and K).

However, some checklists recommended in the 2014 manual update were also used (for example, for qualitative studies [The Critical Appraisal Skills Programme, CASP, (2013) checklist], for effectiveness of intervention/service delivery studies [appropriate NICE quality assessment

checklist]). The eligibility of each study was confirmed by at least 1 member of the GC.

The Quality Assessment of Diagnostic Accuracy Studies – Revised (QUADAS-II) was used for diagnostic studies and was adapted for use with risk assessment studies as follows:

- Index test question signalling question: "If a threshold was used, was it pre-specified?" This was amended to: 'Is information available to facilitate clinical judgment?' (that is, how scores should be translated to risk level)
- Flow and timing signalling question: 'Was there an appropriate interval between index test(s) and reference standard?' This was interpreted as: 'Was there sufficient time for events of interest to occur?'

The CASP clinical prediction rule checklist suggested in the in the 2014 manual update covers similar risk of bias domains as QUADAS II, but the CASP tool does not explicitly cover whether there is sufficient follow up time for events to occur in the study. For this reason QUADAS-II was used and modified to capture this specific aspect.

For some review questions, it was necessary to prioritise the evidence with respect to the UK context (that is, external validity). To make this process explicit, the GC took into account the following factors when assessing the evidence:

- Participant factors (for example, gender, age and ethnicity)
- Provider factors (for example, model fidelity, the conditions under which the intervention was performed and the availability of experienced staff to undertake the procedure)
- Cultural factors (for example, differences in standard care and differences in the welfare system)

It was the responsibility of the GC to decide which prioritisation factors were relevant to each review question in light of the UK context and decisions were recorded in the relevant linking evidence to recommendations (LETR) section.

Double-Sifting

Titles and abstracts of identified studies were screened by two reviewers against inclusion criteria specified in the protocols, until a good inter-rater reliability was observed (percentage agreement ≥90% or Kappa statistics, K>0.60). Any disagreements between raters were resolved through discussion. Initially 10% of references were double-screened. If inter-rater agreement was good, then the remaining references were screened by one reviewer.

Unpublished Evidence

Stakeholders were invited to submit any relevant unpublished data using the call for evidence process set out in the NICE manual. Additionally, authors and principal investigators were approached for unpublished evidence. The GC used a number of criteria when deciding whether or not to accept unpublished data. Firstly, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess risk of bias. Secondly, the evidence must have been submitted with the understanding that data from the study and a summary of the study's characteristics would be published in the full guideline. Therefore, in most circumstances the GC did not accept evidence submitted 'in confidence'. However, the GC recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

Experience of Care

Reviews were sought of qualitative studies that used relevant first-hand experiences of service users and their families, partners or carers. A particular outcome was not specified by the GC. Instead, the review was concerned with narrative data that highlighted the experience of care.

Health Economics Methods

Scoping Searches

A broad preliminary search of the literature was undertaken in July 2014 to obtain an overview of the issues likely to be covered by the scope and help define key areas. Searches were restricted to economic studies and HTA reports and conducted in the following databases:

- EMBASE
- MEDLINE/MEDLINE In-Process
- HTA database (technology assessments)
- NHS Economic Evaluation Database (NHS EED)

Any relevant economic evidence arising from the clinical scoping searches was also made available to the health economist during the same period.

Systematic Literature Searches

After the scope was finalised, a systematic search strategy was developed to locate all the relevant evidence. The balance between sensitivity and specificity was carefully considered and a decision made to utilise a broad approach to searching to maximise retrieval of evidence to all parts of the guideline. Searches were restricted to economic studies and health technology assessment reports and conducted in the following databases:

- EMBASE
- HTA database (technology assessments)
- MEDLINE/MEDLINE In-Process
- National Health Service Economic Evaluation Database (NHS EED)
- PsycINFO

Any relevant economic evidence arising from the clinical searches was also made available to the health economist during the same period.

The search strategies were initially developed for MEDLINE before being translated for use in other databases/interfaces. Strategies were built up through a number of trial searches and discussions of the results of the searches with the review team and GC to ensure that all possible relevant search terms were covered. In order to assure comprehensive coverage, search terms for the guideline topic were kept purposely broad to help counter dissimilarities in database indexing practices and thesaurus terms and imprecise reporting of study interventions by authors in the titles and abstracts of records.

For standard mainstream bibliographic databases (EMBASE, MEDLINE and PsycINFO) search terms for the guideline topic combined with a search filter for health economic studies. For searches generated in topic-specific databases (HTA, NHS EED) search terms for the guideline topic were used without a filter. The sensitivity of this approach was aimed at minimising the risk of overlooking relevant publications, due to potential weaknesses resulting from more focused search strategies. The search terms are set out in full in Appendix F of the full version of the guideline.

Full details of the search strategies and filter used for the systematic review of health economic evidence are provided in Appendix I of the full version of the guideline.

Refer to Section 3.9 in the full version of the guideline for information on reference management, search filters, date and language restrictions, and other search methods.

Inclusion Criteria for Economic Studies

The following inclusion criteria were applied to select studies identified by the economic searches for further consideration:

- Only studies from Organisation for Economic Co-operation and Development countries were included, as the aim of the review was to identify economic information transferable to the UK context.
- Selection criteria based on types of clinical conditions and service users as well as interventions assessed were identical to the clinical literature review.
- Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed and provided that the study's data and results were extractable. Poster presentations of abstracts were excluded.
- Full economic evaluations that compared two or more relevant options and considered both costs and consequences as well as costing analyses that compared only costs between two or more interventions were included in the review. Non-comparative studies were not considered in the review.
- Economic studies were included if they used clinical effectiveness data from a clinical trial, a prospective or retrospective cohort study, a study with a before-and–after design, or from a literature review. Studies with clinical effectiveness based on author's assumptions only were excluded.

Applicability and Quality Criteria for Economic Studies

All economic papers eligible for inclusion were appraised for their applicability and quality using the methodology checklist for economic evaluations recommended in *The Guidelines Manual* (NICE, 2014). All studies that fully or partially met the applicability and quality criteria described in the methodology checklist were considered during the guideline development process. The completed methodology checklists for all economic evaluations considered in the guideline are provided in Appendix R.

Results of the Systematic Search of Economic Literature

The titles of all studies identified by the systematic search of the literature were screened for their relevance to the topic (that is, economic issues and information on health-related quality of life [HRQoL]). References that were clearly not relevant were excluded first. The abstracts of all

potentially relevant studies (41 references) were then assessed against the inclusion criteria for economic evaluations by the health economist. Full texts of the studies potentially meeting the inclusion criteria (including those for which eligibility was not clear from the abstract) were obtained. Studies that did not meet the inclusion criteria, were duplicates, were secondary publications of one study, or had been updated in more recent publications were subsequently excluded. All economic evaluations eligible for inclusion (27 studies in 29 publications) were then appraised for their applicability and quality using the methodology checklist for economic evaluations. Finally, those studies that fully or partially met the applicability and quality criteria set by NICE were considered at formulation of the guideline recommendations.

## Number of Source Documents

See Appendix M (see the "Availability of Companion Documents" field) for information on results of the clinical literature searches and the number of included and excluded studies for each review topic. See also Appendix P of the full version of the guideline for the flow diagram of results of the health economic literature search.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

| Level | Description |
|---|---|
| **High** | Further research is very unlikely to change confidence in the estimate of effect. |
| **Moderate** | Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate. |
| **Low** | Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. |
| **Very Low** | Any estimate of effect is very uncertain. |

## Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Guideline Alliance (NGA) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Clinical Review Methods

Data Extraction

*Quantitative Analysis*

Study characteristics, aspects of methodological quality and outcome data were extracted from all eligible studies, using Review Manager Version 5.3.5 and an Excel-based form (see Appendix L).

In most circumstances, for a given outcome (continuous and dichotomous), where more than 50% of the number randomised to any group were

missing or incomplete, the study results were excluded from the analysis (except for the outcome 'leaving the study early', in which case, the denominator was the number randomised). Where there were limited data for a particular review, the 50% rule was not applied. In these circumstances the evidence was downgraded.

In some circumstances it was not possible to extract any efficacy data for the interventions and outcomes of interest and in such cases the study was excluded from the analysis.

Where possible, outcome data from an intention-to-treat analysis (ITT) (that is, a 'once-randomised-always-analyse' basis) were used. Where ITT had not been used or there were missing data, the effect size for dichotomous outcomes were recalculated using worse-case scenarios (for instance, if the outcome of missing participants was positive, it was assumed that they did not have the positive result). Where conclusions varied between scenarios, the evidence was downgraded.

Where some of the studies failed to report standard deviations (for a continuous outcome) and where an estimate of the variance could not be computed from other reported data or obtained from the study author, the following approach was taken. When the number of studies with missing standard deviations was less than one-third and when the total number of studies was at least 10, the pooled standard deviation was imputed (calculated from all the other studies in the same meta-analysis that used the same version of the outcome measure). In this case, the appropriateness of the imputation was made by comparing the standardised mean differences (SMDs) of those trials that had reported standard deviations against the hypothetical SMDs of the same trials based on the imputed standard deviations. If they converged, the meta-analytical results were considered to be reliable.

When the conditions above could not be met, standard deviations were taken from another related systematic review (if available). In this case, the results were considered to be less reliable and the evidence downgraded.

For continuous outcomes, final scores in each group were the preferred outcome for extraction. However, if final or change scores (from baseline) were not reported for each group in a study (for example, the study reported an F-value, p-value or t-value), the SMD was estimated, if possible using statistical calculator.

The meta-analysis of survival data, such as time to any mood episode, was based on log hazard ratios and standard errors. Since individual participant data were not available in included studies, hazard ratios and standard errors calculated from a Cox proportional hazard model were extracted. Where necessary, standard errors were calculated from confidence intervals (CIs) or p value according to standard formulae (see the Cochrane Reviewers' Handbook 5.1.0). Data were summarised using the generic inverse variance method using Review Manager.

Data from studies included in existing systematic reviews were extracted independently by one reviewer and cross-checked with the existing dataset. Where possible, two independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by one reviewer was checked by the second reviewer. Disagreements were resolved through discussion. Where consensus could not be reached, a third reviewer or GC members resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias.

*Qualitative Analysis*

After transcripts/reviews or primary studies of service user experience were identified, each was read and re-read and sections of the text were collected under different headings using an Excel-based form. Initially the text from the transcripts/reviews was organised using a matrix of service user experience (see Table 5 in the full version of the guideline).

The matrix was formed by creating a table with the eight dimensions of patient-centred care developed by the Picker Institute Europe, down the vertical axis and the key points on a pathway of care (as specified by the GC), across the horizontal axis. With regard to terminology, the GC preferred the term 'person-centred' rather than 'patient-centred', therefore the former is used in the matrix. The Picker Institute's dimensions of patient-centred care were chosen because they are well established, comprehensive and based on research. In addition, a variation of these dimensions has been adopted by the US Institute of Medicine.

Under the broad headings in the matrix, specific emergent themes were identified and coded by two researchers working independently; then, a sample of each other's work (10%) for reliability. Discrepancies or difficulties with the interpretation of study results were resolved through discussion between reviewers or with members of the GC. Overlapping themes and themes with the highest frequency count across all testimonies were extracted and regrouped using the matrix. The findings from the qualitative analysis can be found in Appendix J.

*Evidence Synthesis*

The method used to synthesise evidence depended on the review question and availability and type of evidence (see Appendix F for details). In summary, for questions about the psychometric properties of instruments, reliability, validity and clinical utility were synthesised narratively based

on accepted criteria. For questions about test accuracy, bivariate test accuracy meta-analysis was conducted where appropriate. For questions about the effectiveness of interventions, standard meta-analysis was used where appropriate, otherwise narrative methods were used with clinical advice from the GC. In the absence of high-quality research, formal and informal consensus processes were used.

*Grading the Quality of Evidence*

For questions about the effectiveness of interventions and the organisation and delivery of care, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to grade the quality of evidence from group comparisons for each outcome. Evidence from systematic reviews of Small Case and Small-N (SCSn) designs was graded as 'low' or 'very low' quality without using the formal GRADE approach because specific methodology has not been developed to grade this type of evidence. For questions about the experience of care and the organisation and delivery of care, methodology checklists were used to assess the risk of bias and this information was taken into account when interpreting the evidence. The NGA technical team produced modified GRADE evidence profiles (see below) using GRADEpro guideline development tool (GRADEpro) software (Version 3.6), following advice set out in the GRADE handbook. All staff undertaking GRADE ratings were trained and calibration exercises were used to improve reliability.

For questions about diagnostic accuracy, while the QUADAS framework does not provide an overall quality index for each study, this was deemed important to assist interpretation of the data tools to augment assessment of mental health problems. The terminology used within GRADE (high, moderate, low or very low quality evidence) was adopted. For each of the first three domains (patient selection, index text, reference standard) the GC used the 'risk of bias' and 'concerns about applicability' ratings (low, unclear and high risk for each) to create a 3x3 table (see Table 6 in the full version of the guideline). For domain four (flow and timing), which has only a 'risk of bias' rating, the same method was used, but 'risk of bias' was entered on both axes. The four total domain ratings were then used to generate an overall quality index. For the overall quality rating the GC took the mode classification and subsequent upgrade or downgrade from that point was used; that is, if a study had two ratings of 'high', one of 'moderate' and one of 'very low', then the final quality rating would be 'moderate'. Although there is overlap between the concepts of indirectness in GRADE and applicability in QUADAS it was not explicitly downgraded for indirectness or imprecision because the evidence synthesised in this guideline was derived from similar population or intervention as in protocol.

*Evidence Profiles*

For questions about the effectiveness of interventions and the organisation and delivery of care a GRADE evidence profile was used to summarise both the quality of the evidence and the results of the evidence synthesis for each 'critical' and 'important' outcome (see Appendix N for completed evidence profiles). The GRADE approach is based on a sequential assessment of the quality of evidence, followed by judgment about the balance between desirable and undesirable effects and subsequent decisions about the strength of a recommendation (see Table 7 in the full version of the guideline).

Within the GRADE approach to grading the quality of evidence, the following is used as a starting point:

- Randomised controlled trials (RCTs) without important limitations provide high-quality evidence
- Observational studies without special strengths or important limitations provide low-quality evidence.

For each outcome, quality may be reduced depending on five factors: limitations, inconsistency, indirectness, imprecision and publication bias. For the purposes of the guideline, each factor was evaluated using criteria provided in Table 8 of the full version of the guideline.

For observational studies without any reasons for down-grading, the quality may be up-graded if there is a large effect, all plausible confounding would reduce the demonstrated effect (or increase the effect if no effect was observed), or there is evidence of a dose-response gradient (details would be provided under the 'other' column).

Presenting Evidence to the Guideline Committee

Study characteristics tables and, where appropriate, forest plots generated with Review Manager Version 5.3 and GRADE summary of findings tables (see below) were presented to the GC.

Where meta-analysis was not appropriate and/or possible, the reported results from each primary-level study were reported in the study characteristics table and presented to the GC. The range of effect estimates were included in the GRADE profile and where appropriate, described narratively.

The GC were also provided with evidence statements reflecting the key findings, the quantity, quality and consistency of the evidence. Evidence statements were prioritised for the critical outcomes, especially when the evidence contained multiple correlated outcomes.

*Summary of Findings Tables*

Summary of findings tables generated from GRADEpro were used to summarise the evidence for each outcome and the quality of that evidence. Table 9 in the full version of the guideline is an example of a GRADE summary of findings table. The summary of findings tables provide anticipated comparative risks, which are especially useful when the baseline risk varies for different groups within the population. Table 10 in the full version of the guideline is an aid to the interpretation of the psychometric scales used as outcomes in some of the summary of findings tables.

*Extrapolation*

When answering review questions, if there was no direct evidence from a primary dataset, based on the initial search for evidence, it may be appropriate to extrapolate from another data set. Refer to the full version of the guideline for principles that were used in data extrapolation.

Refer to Section 3.8 in the full version of the guideline for additional information.

Health Economic Methods

The aim of the health economics approach was to contribute to the guideline's development by providing evidence on the cost effectiveness of interventions and services covered in this guideline. This was achieved by a systematic literature review of existing economic evidence in all areas covered in the guideline.

Economic modelling was planned to be undertaken in areas with likely major resource implications, where the current extent of uncertainty over cost effectiveness was significant and economic analysis was expected to reduce this uncertainty, in accordance with *The Guidelines Manual* (NICE, 2014). Prioritisation of areas for economic modelling was a joint decision between the Health Economist and the GC. The rationale for prioritising review questions for economic modelling was set out in an economic plan agreed between NICE, the GC, the Health Economist and the other members of the NGA technical team. The following economic questions were selected as key issues to be addressed by economic modelling:

- Interventions to promote mental health and wellbeing and modifications needed to psychological, social, pharmacological or physical interventions recommended in other NICE guidance
- Interventions for adults with a personality disorder
- Interventions for adults with a paraphilic disorder
- Recognition and assessment tools

In addition, literature on the health-related quality of life (HRQoL) of people covered by this guideline was systematically searched to identify studies reporting appropriate utility scores that could be utilised in a cost-utility analysis.

The identified clinical evidence on the areas prioritised for economic modelling was very sparse and allowed only a simple exploratory cost analysis assessing the impact of therapeutic community treatment for substance misuse treatment in imprisoned adults. The methods and results of this analysis are reported in Chapter 7 of the full version of the guideline.

In areas where modelling was not possible, the GC took into consideration resource implications and anticipated the cost effectiveness of interventions and services for people with mental health problems who are in contact with the criminal justice system when making recommendations.

Applicability and Quality Criteria for Economic Studies

All economic papers eligible for inclusion were appraised for their applicability and quality using the methodology checklist for economic evaluations recommended in *The Guidelines Manual* (2014). All studies that fully or partially met the applicability and quality criteria described in the methodology checklist were considered during the guideline development process. The completed methodology checklists for all economic evaluations considered in the guideline are provided in Appendix R.

## Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Informal Consensus

## Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Guideline Alliance (NGA) on behalf of the

National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance and related appendices.

Who Has Developed This Guideline?

The Guideline Committee (GC) was convened by the NGA and supported by funding from NICE. The GC included people with mental health problems who have been in contact with the criminal justice system and carers and professionals from psychiatry, clinical psychology, general practice, nursing, psychiatric pharmacy, Her Majesty's (HM) Prison Service, police, probation service providers and the private and voluntary sectors.

Staff from the NGA provided leadership and support throughout the process of guideline development, undertaking systematic searches, information retrieval, appraisal and systematic review of the evidence. Members of the GC received training in the process of guideline development from NGA staff and the service users and carers received training and support from the NICE Patient and Public Involvement Programme. The NICE Guidelines Technical Adviser provided advice and assistance regarding aspects of the guideline development process.

The Guideline Committee

During the consultation phase, members of the GC were appointed by an open recruitment process. GC membership consisted of professionals in psychiatry, clinical psychology, nursing, social work, speech and language therapy and general practice; academic experts in psychiatry and psychology; commissioning managers; and carers and representatives from service user and carer organisations. The guideline development process was supported by staff from the NGA, who undertook the clinical and health economic literature searches, reviewed and presented the evidence to the GC, project managed the process and contributed to drafting the guideline.

Guideline Committee Meetings

A total of 12 GC meetings were held between January 2015 and July 2016. During each day-long GC meeting, in a plenary session, review questions and clinical and economic evidence were reviewed and assessed and recommendations formulated.

Service Users and Carers

Individuals with direct experience of services gave an integral service-user focus to the GC and the guideline. The GC included a carer and two service users with mental health problems and experience of the criminal justice system. They contributed as full GC members to writing the review questions, providing advice on outcomes most relevant to service users and carers, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline and bringing service user research to the attention of the GC. In drafting the guideline, they met with the NGA team on several occasions to develop the chapter on experience of care and they contributed to writing the guideline's introduction and identified recommendations from the service user and carer perspective.

Expert Advisers

Expert advisers, who had specific expertise in one or more aspects of treatment and management relevant to the guideline, assisted the GC, commenting on specific aspects of the developing guideline and making presentations to the GC. Appendix C lists those who agreed to act as expert advisers.

National and International Experts

National and international experts in the area under review were identified through the literature search and through the experience of the GC members. These experts were contacted to identify unpublished or soon-to-be published studies, to ensure that up-to-date evidence was included in the development of the guideline. They informed the GC about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost effectiveness of treatment and trial data if the GC could be provided with full access to the complete trial report. Appendix E lists researchers who were contacted.

Using NICE Evidence Reviews and Recommendations from Existing NICE Clinical Guidelines

When review questions overlapped and evidence from another guideline applied to a question in the current guideline, it was desirable and practical to incorporate or adapt recommendations published in NICE guidelines. Adaptation refers to the process by which an existing recommendation is modified in order to facilitate its placement in a new guideline. Incorporation refers to the placement of a recommendation that was developed for another guideline into a new guideline, with no material changes to wording or structure. In most cases incorporation was not used, as cross-referring to the other guideline was all that was necessary.

Refer to the full version of the guideline for detailed discussion of the criteria for incorporation and adaptation.

Roles and Responsibilities

The guideline review team, in consultation with the guideline Facilitator and Chair, were responsible for identifying overlapping questions and deciding if it would be appropriate to incorporate or to adapt. For adapted recommendations, at least two members of the GC for the original guideline were consulted to ensure the meaning and intent of the original recommendation was preserved. The GC confirmed the process had been followed, confirmed that there was insufficient evidence to make new recommendations and agreed all adaptations to existing recommendations.

Drafting of Adapted Recommendations

The drafting of adapted recommendations conformed to standard NICE procedures for the drafting of guideline recommendations, preserved the original meaning and intent and aimed to minimise the degree or re-writing and re-structuring.

From Evidence to Recommendations

Once the clinical and health economic evidence was summarised, the GC drafted the recommendations. In making recommendations, the GC took into account the quality of the evidence, the trade-off between the benefits and harms of the intervention/instrument, as well as other important factors such as the trade-off between net health benefits and resource use, values of the GC and society, the requirements to prevent discrimination and to promote equality and the GC's awareness of practical issues.

Finally, to show clearly how the GC moved from the evidence to the recommendations, each chapter (or sub-section) has a section called 'recommendations and link to evidence'. Underpinning this section is the concept of the 'strength' of a recommendation. This takes into account the quality of the evidence but is conceptually different. Some recommendations are 'strong' in that the GC believes that the vast majority of healthcare professionals and service users would choose a particular intervention if they considered the evidence in the same way that the GC has. This is generally the case if the benefits clearly outweigh the harms for most people and the intervention is likely to be cost effective. However, there is often a closer balance between benefits and harms and some service users would not choose an intervention whereas others would. This may happen, for example, if some service users are particularly averse to some side effect and others are not. In these circumstances the recommendation is generally weaker, although it may be possible to make stronger recommendations about specific groups of service users. The strength of each recommendation is reflected in the wording of the recommendation, rather than by using ratings, labels or symbols. The word 'offer' was used for recommendations with strong evidence whereas 'consider' was used to make recommendations with limited evidence (see the "Rating Scheme for the Strength of the Recommendations" field). Where the GC identified areas in which there were uncertainties or where robust evidence was lacking, they developed research recommendations. Those that were identified as 'high priority' were developed further in the NICE version of the guideline and presented in Appendix G.

Method Used to Answer a Review Question in the Absence of Appropriately Designed, High-Quality Research

In the absence of appropriately designed, high-quality research (including indirect evidence where it would be appropriate to use extrapolation), both formal and informal consensus processes were adopted.

*Formal Method of Consensus*

The modified nominal group technique was chosen due to its suitability within the guideline development process. The method is concerned with deriving a group decision from a set of expert individuals and has been identified as the method most commonly used for the development of consensus in health care. The nominal group technique requires participants to indicate their agreement with a set of statements about the intervention(s) of concern. These statements were developed by the NGA technical team drawing on the available sources of evidence on the methods of delivery and outcomes of the interventions. These sources of evidence could be supplemented by advice from external experts in the intervention(s). Agreement with the statements were rated on a nine-point Likert scale, where one represented least agreement and nine represented most agreement. In the first round participants indicated the extent of their agreement with the statements and also provided written comment on their reason for any disagreement and how the statement could be modified.

In round one, members were presented with an overview of the modified nominal group technique, a short summary of the available evidence, a consensus questionnaire containing the statements and instructions on the use of the questionnaire. Members were asked to rate their agreement with the statements taking into account the available evidence and their expertise. For the purpose of determining agreement, ratings were grouped into three categories to calculate the percentage agreement: 1–3 (inappropriate strategy), 4–6 (uncertain), or 7–9 (appropriate strategy or adaptation).

Where possible, in the afternoon of the GC meeting or at the subsequent GC meeting, anonymised distributions of responses to each statement were given to all members, together with members' additional comments and a ranking of statements based on consensus percentage agreement. Those statements with 80% or greater agreement were used to inform the drafting of recommendations, where appropriate taking into account the initial comments from and subsequent discussions with the GC.

For statements where there was 60% to 80% agreement a judgement was made based on the nature of the comments from the GC. If it appeared from the comments that the general principle included within the statement was agreed but that the comments could be addressed with some minor amendments incorporating the comments, the statements were used to inform the development of recommendations. Other statements that fell within this range were re-drafted based on the comments from the first rating and re-rated as in round one (round two). If agreement at 80% or above on the re-rated was achieved, the statements were used to inform recommendations. Those that did not were discarded.

Any distribution of ratings with less than 60% agreement in round one was generally regarded as no consensus and discarded, unless obvious and addressable issues were identified from the comments.

*Informal Method of Consensus*

The informal consensus process involved a group discussion of what is known about the issues. The views of GC were synthesised narratively by a member of the review team and circulated after the meeting. Feedback was used to revise the text, which was then included in the appropriate evidence review chapter.

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Some recommendations can be made with more certainty than others, depending on the quality of the underpinning evidence. The Guideline Committee makes a recommendation based on the trade-off between the benefits and harms of a system, process or an intervention, taking into account the quality of the underpinning evidence. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The Guideline Committee usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the Guideline Committee uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The Guideline Committee uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of people, a system, process or an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer…') are used when the Guideline Committee is confident that an intervention will not be of benefit for most people.

Interventions That Could Be Used

The Guideline Committee uses 'consider' when confident that a system, process or an intervention will do more good than harm for most people, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the person's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the person.

## Cost Analysis

Presentation of Economic Evidence

The economic evidence considered in the guideline is provided in the respective evidence chapters of the full version of the guideline, following presentation of the relevant clinical evidence. The references to included studies and the respective evidence tables with the study characteristics and results are provided in Appendix S. Characteristics and results of all economic studies considered during the guideline development process are summarised in economic evidence profiles provided in Appendix T. See the "Availability of Companion Documents" field for the full version of the guideline and related appendices.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

Validation of the Guideline

Registered stakeholders had an opportunity to comment on the draft guideline, which was posted on the National Institute for Health and Care Excellence (NICE) Web site during the consultation period. Following the consultation, all comments from stakeholders and experts were responded to and the guideline updated as appropriate. NICE also reviewed the guideline and checked that stakeholders' comments had been addressed.

Following the consultation period, the Guideline Committee (GC) finalised the recommendations and the National Guideline Alliance (NGA) produced the final documents. These were then submitted to NICE for a quality assurance check. Any errors were corrected by the NGA, then the guideline was formally approved by NICE and issued as guidance to the National Health Service (NHS) in England and Wales.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The type of evidence supporting each review area is detailed in the full version of the guideline (see the "Availability of Companion Documents" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- Improved mental health and wellbeing in people who are in contact with the criminal justice system
- Improved training and education for health, social care and criminal justice practitioners

Refer to the "Trade-off between clinical benefits and harms" sections of the full version of the guideline (see the "Availability of Companion Documents" field) for details about benefits of specific interventions.

### Potential Harms

- Based on their experience, the Guideline Committee (GC) did not consider that there were significant harms associated with the use of psychological interventions, but were concerned that pharmacological interventions may be associated with illicit drug use and, in particular, harms associated with accidental or planned overdose.
- Anti-adrenergic drugs are associated with significant side effects, including breast development in men. These side effects are also associated with a high drop-out and poor compliance with treatment regimens.

See the "Trade-off between clinical benefits and harms" sections in the full version of the guideline (see the "Availability of Companion Documents" field) for details about harms of specific interventions.

## Qualifying Statements

### Qualifying Statements

- The recommendations in this guideline represent the view of the National Institute for Health and Care Excellence (NICE), arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.
- Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

# Implementation of the Guideline

## Description of Implementation Strategy

Putting This Guideline into Practice

The National Institute for Health and Care Excellence (NICE) has produced tools and resources to help put this guideline into practice.

Putting recommendations into practice can take time. How long may vary from guideline to guideline, and depends on how much change in practice or services is needed. Implementing change is most effective when aligned with local priorities.

Changes recommended for clinical practice that can be done quickly – like changes in prescribing practice – should be shared quickly. This is because healthcare professionals should use guidelines to guide their work – as is required by professional regulating bodies such as the General Medical and Nursing and Midwifery Councils.

Changes should be implemented as soon as possible, unless there is a good reason for not doing so (for example, if it would be better value for money if a package of recommendations were all implemented at once).

Different organisations may need different approaches to implementation, depending on their size and function. Sometimes individual practitioners may be able to respond to recommendations to improve their practice more quickly than large organisations.

Here are some pointers to help organisations put NICE guidelines into practice:

1. Raise awareness through routine communication channels, such as email or newsletters, regular meetings, internal staff briefings and other communications with all relevant partner organisations. Identify things staff can include in their own practice straight away.
2. Identify a lead with an interest in the topic (it could be someone who is already championing oral health in your local area) to motivate and support others to use the guideline and make service changes, and to find out about any significant issues locally.
3. Carry out a baseline assessment against the recommendations to find out whether there are gaps in current service provision.
4. Think about what data you need to measure improvement and plan how you will collect it. You may want to work with other health and social care organisations and specialist groups to compare current practice with the recommendations. This may also help identify local issues that will slow or prevent implementation.
5. Develop an action plan, with the steps needed to put the guideline into practice, and make sure it is ready as soon as possible. Big, complex changes may take longer to implement, but some may be quick and easy to do. An action plan will help in both cases.
6. For very big changes include milestones and a business case, which will set out additional costs, savings and possible areas for disinvestment. A small project group could develop the action plan. The group might include the guideline champion, a senior organisational sponsor, staff involved in the associated services, finance and information professionals.
7. Implement the action plan with oversight from the lead and the project group. Big projects may also need project management support.
8. Review and monitor how well the guideline is being implemented through the project group. Share progress with those involved in making improvements, as well as relevant boards and local partners.

NICE provides a comprehensive programme of support and resources to maximise uptake and use of evidence and guidance. See the into practice pages for more information.

Also see Leng G, Moore V, Abraham S, editors (2014). Achieving high quality care – practical experience from NICE. Chichester: Wiley.

### Implementation Tools

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

National Guideline Alliance. Mental health of adults in contact with the criminal justice system. London (UK): National Institute for Health and Care Excellence (NICE); 2017 Mar 21. 40 p. (NICE guideline; no. 66).

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2017 Mar 21

### Guideline Developer(s)

National Guideline Alliance - National Government Agency [Non-U.S.]

## Source(s) of Funding

This guideline has been commissioned by the National Institute for Health and Care Excellence (NICE) and developed within the National Guideline Alliance (NGA).

## Guideline Committee

Guideline Committee (GC)

## Composition of Group That Authored the Guideline

*Guideline Committee Members*: Nick Kosky, Medical Director & Consultant Psychiatrist, Dorset Healthcare University Foundation Trust, Forston Clinic; Richard Byng (*Deputy Chair*), Professor of Primary Care Research, Primary Care Group, Plymouth University Peninsula Schools of Medicine and Dentistry, Deputy Director, Peninsula CLAHRC for the south west, General Practitioner, Mount Gould Primary Care Centre and GP with Special Interest in Mental Health (Honorary, Plymouth Community Healthcare and The Zone, Plymouth); Vikki Baker, Joint Service Director, Consultant Clinical Psychologist, Resettle; Annie Bartlett, Reader and Honorary Consultant in Forensic Psychiatry SGUL and CNWL FT, Clinical Director Offender Care CNWL FT; Diana Binding, Assistant Chief Executive – Gwent, Wales Community Rehabilitation Service (CRC); Richard Bradshaw (*Chair, Physical Health in Prisons, NICE Guideline*); Steffan Davies, Consultant Forensic Psychiatrist, Offender Health Services, Northamptonshire Healthcare NHS Foundation Trust; Stephen Habgood, Former Prison Governor and Chairman of PAPYRUS Prevention of Young Suicide; Kay Isaacs, Manager, Criminal Justice Mental Health Team, Abertawe Bro Morgannwg University Health Board; Sunil Lad, Principal Counselling Psychologist, Offender Health, Northamptonshire Healthcare Foundation Trust; Naomi Lumsdaine, Women Prisoners' Caseworker, Prisoners' Advice Service, Qualified barrister; Kerry Manson, Clinical Psychologist; Tony O'Connell, Detective Constable, Dorset Police; Leroy Simpson, Service User; Nicole Stanbury, Service User; Julia Tabreham, Chief Executive, Carers Federation Ltd (Retired); Jenny Talbot, Director, Care not Custody, Prison Reform Trust; Mark Warren, Forensic Liaison Practitioner, CWM TAF University Health Board, Wales; Geoffrey White, Prison Officer; Joanne White, Primary Care Mental Health Team Leader, HMP Leeds

## Financial Disclosures/Conflicts of Interest

All Guideline Committee (GC) members made formal declarations of interest at the outset, which were updated at every GC meeting. See Appendix B of the full version of the guideline (see the "Availability of Companion Documents" field) for declarations of interests made by the members of the GC.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub and eBook formats from the NICE Web site .

## Availability of Companion Documents

The following are available:

- Mental health of adults in contact with the criminal justice system. Full guideline. London (UK): National Institute for Health and Care Excellence (NICE); 2017 Mar. 343 p. (NICE guideline; no. 66). Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Mental health of adults in contact with the criminal justice system. Appendices. (NICE guideline; no. 66). Available from the NICE Web

site .

- Mental health of adults in contact with the criminal justice system. Baseline assessment tool. London (UK): National Institute for Health and Care Excellence; 2017 Mar. (NICE guideline; no. 66). Available from the NICE Web site .
- Mental health of adults in contact with the criminal justice system. Resource impact report. London (UK): National Institute for Health and Care Excellence; 2017 Mar. 13 p. (NICE guideline; no. 66). Available from the NICE Web site .
- Mental health of adults in contact with the criminal justice system. Resource impact template. London (UK): National Institute for Health and Care Excellence; 2017 Mar. (NICE guideline; no. 66). Available from the NICE Web site .
- Developing NICE guidelines: the manual. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Oct. Available from the NICE Web site .

## Patient Resources

The following is available:

- Mental health of adults in contact with the criminal justice system. Information for the public. London (UK): National Institute for Health and Care Excellence; 2017 Mar. 5 p. (NICE guideline; no. 66). Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub and eBook formats from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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